



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,559	11/30/2001	Owe Orwar	003300-868	3828
21874	7590	01/27/2005	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			HANLEY, SUSAN MARIE	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/996,559	Applicant(s) ORWAR ET AL.	
	Examiner Susan Hanley	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1651

DETAILED ACTION

The examiner for this application is Susan Hanley. Her contact information can be found at the end of this Office action.

Election/Restrictions

The restriction requirement of 10/10/2004 is withdrawn.

Claims 1-73 are presented for examination.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

Claims 8 and 9 are objected to because of the following informalities: In line 2 of each claim the phrase "substances that activates" lacks agreement in number. It is suggested that it be changed to "substances that activate". Appropriate correction is required.

Claims 26 is objected to because the phrase "on agent" should be "one agent."

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 54-61 and 63-73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 54-61 and 64-73 are

Art Unit: 1651

drawn to methods of in vitro fertilization, cloning, cell transfection, production of monoclonal antibodies, preparation of a hybridoma, manipulation of a composition of a cellular membrane, the delivery of a well-defined volume of a substance and stem cell research according to the method of claim 1 or by using the apparatus of claim 41. Claim 63 is drawn to a biosensor comprising the apparatus of claim 41. The specification simply lists the methods and biosensor in claims 54-61 and 63-73 as applications for the disclosed method and apparatus with no further disclosure (p. 20, instant specification).

To fulfill the written description requirement, a specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, the written description requirement is satisfied "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Accordingly, an adequate written description of the methods of claims requires more than a mere statement that the capabilities offered by the method and apparatus of claims 1-53. Whether or not the disclosure provides an enabling disclosure, the specification fails to provide a written description of the steps to employ the generic method and apparatus of claims 1-53 to carry out the wide range of claimed applications. Simply stating that a particular method or apparatus is suitable for highly technical, specialized application does not convey any distinguishing information concerning how to carry out said specialized applications. There is no further information in the application pertaining to any discussion that demonstrates how to employ the apparently novel apparatus and method of the instant application to the claimed fields of application. Further, the instant specification fails to describe what is meant by the term "biosensor" and how the claimed apparatus can be adapted for such use. Thus, although the

Art Unit: 1651

claimed method and apparatus are described by the specification, the specification lacks any description related to the specialized employment of said method or apparatus to the claimed fields of application.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, a listing of specialized application of a general method or an apparatus is not a description of the claimed methods or biosensor.

Claim 62 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 62 is drawn to a biosensor prepared to the method of claim 1. Claim 1 is drawn to a method of manipulating a cell. It is not related to the manufacture of an apparatus. Further, the instant specification does not provide any written description related to preparing a biosensor according to a method of manipulating a cell. In conclusion, claim 62 is rejected because the specification fails to provide a description that supports a claim of preparing a biosensor via a method of manipulating a cell.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 12, 14, 59-62 and 64-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1651

Claim 7 is rejected because it is unclear how the agents of claim 5 that are delivered in a parallel manner can also be delivered in a combinatorial manner. It is unclear if said types of delivery are occurring at the same time or at different times.

Claims 12 and 14 are rejected because the term "flows" is unclear. It is not clear if the claim is referring to "flow" as a means or if there is more than one "flow" for each means.

Claims 59-62 and 64-73 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: How the claimed method or apparatus is employed to carry out the specialized claimed method. It is unclear what other steps are required to utilize the claimed method and apparatus to achieve the intended purposes of claims 59-62 and 64-73.

Claims 66-67 are rejected because the phrase "manipulation of a composition of a cellular membrane" is vague and indefinite. It is unclear if the claim is intended to bring an exogenous composition to a cell membrane for some unspecified purpose or if the phrase is directed to manipulating a composition that comprises some particular part of a cell membrane.

Claims 72-73 are rejected because the phrase "a method for conducting stem cell research" is vague and indefinite. Stem cell research is a field of scientific endeavor. It does not relate to one definite, well defined method. It is unclear how the claimed method or apparatus can be used for an entire field of scientific endeavor.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Art Unit: 1651

Claims 1-73 are rejected under 35 U.S.C. 102(a) as being anticipated by Strömberg et al. (30 Nov 2000 - web publication date).

Strömberg et al. (30 Nov 2000) disclose the instantly claimed methods and apparatus. Strömberg et al. (30 Nov 2000) has a different authorship, and therefore is by another" until shown otherwise. The instant application lists Mattias Karlsson as an inventor but is not listed as an author in the reference. Frida Ryttsén and Maximillian Davidson were listed as authors but do not appear as inventors.

Applicant has responded to the rejection made under 35 U.S.C. 102(a) and 102(f) in the previous office action with a declaration regarding the inventorship. The declaration lists that added Frida Ryttsén and Maximillian Davidson did not contribute to the conception of the invention and that Mattias Karlsson did help conceive of the invented subject matter but did not literally write the article or perform the experiments represented by the figures in the article.

The declaration overcomes the rejection with respect to Frida Ryttsén and Maximillian Davidson. However, the inventive entity of the reference is still different from that of the application and the declaration, while effective to remove Ryttsén and Davidson, is insufficient to add M. Karlsson to the reference. Applicant is directed to MPEP 2132 and 715 for discussion on overcoming rejections made under 102(a), particularly regarding "swearing back" to overcome the rejection.

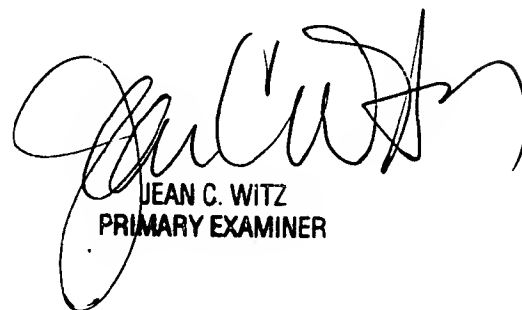
Art Unit: 1651

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan Hanley
Patent Examiner
AU 1651



JEAN C. WITZ
PRIMARY EXAMINER